

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in August 2014.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-043

Trade Name: SYNOVEX Choice®
Ingredients: Trenbolone acetate and estradiol benzoate
Sponsor: Zoetis Inc.
Approval Date: August 3, 2014

This supplement provides for the addition of a new indication for increased rate of weight gain and improved feed efficiency in heifers fed in confinement for slaughter.

NADA Number: 140-833

Trade Name: Ivomec® Plus Injection for Cattle
Ingredients: Ivermectin and clorsulon
Sponsor: Merial Ltd.
Approval Date: August 13, 2014

This supplement is to decrease the withdrawal period from 49 days to 21 days.

NADA Number: 141-342

Trade Name: Alfaxan®
Ingredients: Alfaxalone
Sponsor: Jurox Pty. Ltd.
Approval Date: August 1, 2014

This supplement provides for the approval of the revised labeling components to reflect the placement of alfaxalone into Schedule IV controlled substance classification.

Patent Additions

NADA Number: 141-426

Patent number: 8,796,464
Expiration Date: July 29, 2029